SCIENTIFIC PAPER JSLS

Randomized Prospective Study of Totally Extraperitoneal Inguinal Hernia Repair: Fixation Versus No Fixation of Mesh

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ABSTRACT

Background: Fixation of the mesh during laparoscopic totally extraperitoneal (TEP) inguinal hernia repair is thought to be necessary to prevent recurrence. However, mesh fixation may increase postoperative pain and lead to an increased risk of complications. We questioned whether elimination of fixation of the mesh during TEP inguinal hernia repair leads to decreased postoperative pain or complications, or both, without an increased rate of recurrence.

Methods: A randomized prospective single-blinded study was carried out in 40 patients who underwent laparoscopic TEP inguinal hernia repair with (Group A=20) or without (Group B=20) fixation of the mesh.

Results: Patients in whom the mesh was not fixed had shorter hospital length of stay (8.3 vs 16.0 hours, P=0.01), were less likely to be admitted to the hospital (P=0.001), used less postoperative narcotic analgesia in the PACU (P=0.01), and were less likely to develop urinary retention (P=0.04). No significant differences occurred in the level of pain, time to return to normal activity, or the difficulty of the operation between the 2 groups. No hernia recurrences were observed in either group (follow-up range, 6 to 30 months, median=19).

Conclusions: Elimination of tack fixation of mesh during laparoscopic TEP inguinal hernia repair significantly reduces the use of postoperative narcotic analgesia, hospital length of stay, and the development of postoperative urinary retention but does not lead to a significant reduction in postoperative pain. Eliminating tacks does not lead to an increased rate of recurrence.

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Key Words: Hernia, Urinary retention, Endoscopic, TEP, Laparoscopic.

INTRODUCTION

Approximately 15% of all inguinal hernias are repaired endoscopically, primarily in a preperitoneal fashion (totally extraperitoneal=TEP) in which the hernia defect is covered with a prosthetic mesh that is fixed to the abdominal wall with spiral tacks, clips, or sutures. The need for fixation of the mesh is controversial. Some have suggested that fixation of mesh during endoscopic TEP inguinal hernia repair is necessary to prevent hernia recurrence.[1] However, fixation of the mesh is thought to contribute to increased postoperative pain and the risk of nerve injury. Nerve injury has been estimated to occur in 2% to 4% of laparoscopic inguinal hernia repairs with the most commonly injured nerves being the femoral branch of the genitofemoral nerve and the lateral femoral cutaneous nerve.[2] The purpose of this study was to determine whether elimination of tacking the mesh during endoscopic TEP inguinal hernia repair results in decreased postoperative pain or complications, or both, without increasing the incidence of hernia recurrence.

METHODS

Patients

This study was conducted as a randomized, prospective, single-blinded (blinded to patient and nurses, but not to surgeons) study following approval by the Institutional Review Board and with written informed consent of all participants. All males between the ages of 18 and 100 years of age undergoing TEP inguinal hernia repair were eligible. Exclusion criteria included patients who did not meet the criteria for general anesthesia, had a history of radical prostatectomy or low anterior colon/rectal resection, or those with an underlying coagulopathy. Forty patients were enrolled in the study between January 2002 and January 2004. Patients were

computer randomized preoperatively according to age and BMI into 2 groups: endoscopic preperitoneal inguinal hernia repair[1] with or[2] without tacking of the mesh prosthesis.

Surgical Technique

TEP endoscopic inguinal hernia repairs were performed with the patient under general anesthesia by using a midline, 3-trocar technique. Polypropylene mesh (Prolene; Ethicon, Summerville, NJ) was trimmed to the appropriate size to cover the entire myopectineal orifice including the hernia defect(s). The mesh was coapted to Cooper's ligament and the anterior abdominal wall using 5 to 8 spiral tacks in patients enrolled in the tacking arm of the study (Group A). A pre-formed 15x10-cm mesh (3D-MAX, Davol Inc., Cranston, NJ) was used without tack fixation in patients enrolled in the nontacking arm of the study (Group B).

Pre- and Postoperative Assessment

Preoperatively, patients were asked to rate their level of pain according to a Likert scale (0=no pain, 10=most severe pain). Intraoperatively, surgeons were asked to rate the difficulty of the operation on a scale of 1 to 3 (1=no difficulty, 2=somewhat difficult, 3=very difficult). Pertinent pre- and intraoperative data was recorded from the medical records. Patients' level of pain, pain medications administered, and length of stay in the Post Anesthesia Care Unit (PACU) was obtained from the medical records. Patients were assessed for pain levels, activity levels, and the use of pain medications upon return to their hospital rooms, immediately before discharge, and at 1, 4, and 12 months postoperatively using a standardized telephone script. The use of pain medications was categorized according to the number of doses of parenteral narcotics, oral narcotics, or oral non-narcotic pain medicines.

Statistical Analysis

Continuous data are presented as mean ± standard deviation, and discrete data are presented as counts and percentages. Continuous data following a Gaussian distribution were compared using 2-sample *t* tests. Non-Gaussian data were compared using Wilcoxon rank sum tests. Discrete nominal data were analyzed using a chi-square test while discrete ordinal data were compared using a Mantel-Haenszel chi-square test. All statistical tests were 2-sided, and the threshold of significance was set at $P \leq 0.05$. The sample size used provided 80% power to detect differences in means of continuous variables ≥ 0.91 standard deviations. Applied to a small set of historical data, this translates into a difference in means of 2.1 points of perceived pain (on a 0–10 Likert scale) upon arrival in the postanesthesia care unit.

RESULTS

Randomization (Group A=tacks, Group B=no tacks) and follow-up were complete in all 40 male subjects **(Table 1)**. Group A patients had higher levels of pain throughout the postoperative course with the exception of the first hour spent on the hospital floor **(Table 2)**; however, none of these comparisons were statistically significant. Level of pain experienced by patients postoperatively correlated with the use of postoperative narcotic analgesia. Additionally, patients in whom mesh was not fixed (Group B) used significantly less postoperative narcotic analgesia in the immediate postoperative period compared with patients in whom mesh was fixed. While the use of postoperative narcotics by Group B patients was also decreased during the first hour on the hospital floor and at discharge compared with Group A patients, it did not reach statistical significance.

Group B patients experienced reduced hospital length of stay and were less likely to be admitted to the hospital for 23-hour observation compared with Group A patients

Table 1.
Patient Demographics

	Fixed Mesh (n=20)*	Nonfixed Mesh (n=20)*	P Value
Age	56.3±11.5	54.6±16.1	
BMI	27.0±3.6	27.2±3.1	0.70
Total Hernias	26	27	0.86
Indirect	10 (39.0)	12 (44.4)	0.75
Direct	13 (50.0)	12 (44.4)	
Pantaloon	3 (11.0)	2 (7.4)	
Femoral	0 (0.0)	1 (3.7)	
Site of Hernia			
Unilateral	14 (75.0)	13 (65.0)	>0.99
Bilateral	6 (25.0)	7 (35.0)	
Type of Hernia			
Primary	26 (100.0)	24 (88.9)	0.24
Recurrent	0 (0.0)	3 (1.1)	

*Data expressed as mean±SD or proportion (percentage of population).

Table 2.
Perioperative Data

	Fixed Mesh (n=20)*	Nonfixed Mesh (n=20)*	P Value
Operative Time (min)	66.3±26.1	60.9±20.0	0.59
Hospital Length of Stay (hrs)	16.0±11.6	8.3±5.2	0.01
Admitted to Hospital	10 (50.0)	2 (10.0)	0.001
Pain (0–10 Likert Scale)			
Preop	0.9±1.7	0.5±1.0	0.44
Enter PACU†	1.9±2.3	1.1±1.6	0.25
Leave PACU†	2.3±1.7	1.6±1.6	0.19
1st Hr on Floor	2.8±1.5	2.9±2.2	0.87
Prior to Discharge	1.8±1.6	1.4±1.2	0.48
1 Wk Postop	1.5±1.3	1.2±1.0	0.40
4 Wks Postop	0.8±1.7	0.3±0.8	0.15
Postop Narcotic Use (morphine equivalents)			
PACU	2.9±5.1	0.1±0.6	0.01
1st Hr on Floor	1.0±2.7	0.9±2.2	0.79
Prior to Discharge	4.5±9.7	2.4±4.6	0.43
Urinary Retention	7 (35.0)	1 (5.0)	0.04
Difficulty of Operation			
Very Difficult	2	1	
Somewhat Difficult	8	6	
Not Difficult	10	13	

*Data expressed as mean±SD or proportion (percent of population).

†PACU=Post Anesthesia Care Unit.

(Table 2). Group B patients had a mean hospital length of stay of 8.3±5.2 hours compared with 16.0±11.6 hours in Group A patients (P=0.01). Only 2 out of 20 (10%) Group B patients were admitted for observation compared with 10 out of 20 (50%) Group A patients (P=0.001). Admission for 23-hour observation was related to nausea/vomiting (n=1), urinary retention (n=1) (Group B) and urinary retention (n=7), nausea/vomiting (n=3) (Group A). No significant difference existed in the amount of intra- or postoperative intravenous fluid administered to either group of patients. Use of preformed mesh without fixation did not result in increased operative difficulty or operative time.

No difference was noted in the time to return to normal activity with lifting restrictions between the 2 groups. None of the patients in either group returned to normal activity at one week. Twelve out of 20 (60%) Group A patients returned to normal activity with lifting restrictions at 4 weeks compared with 16 out of 20 (80%) Group B patients (P=0.24).

Long-term follow-up (range, 6 to 30 months; median, 9 months) information was available on 37 patients for recurrence (93%) and 34 patients for pain (85%). No recurrences or nerve injuries were reported. Three out of 20 (15%) Group A patients reported mild pain at last follow-up, while 5 out of 18 (28%) Group B patients reported pain at last follow-up (P=0.43). The 20 Group A patients had a mean Likert$^{0-10}$ pain level of 0.53±1.30, while the 18 Group B patients had a mean pain level of 0.88±1.50 (P=0.35).

DISCUSSION

The necessity of fixing mesh to prevent recurrence of hernias following endoscopic preperitoneal inguinal hernia repair is controversial. Our results suggest that endoscopic preperitoneal inguinal hernia repair without mesh fixation does not appear to increase the incidence of hernia recurrence. Endoscopic TEP inguinal hernia repair without mesh fixation leads to decreased hospital stays and fewer admissions for 23-hour observation compared with TEP with mesh fixation to the abdominal wall. Inserting preformed, tackless mesh does not appear to make the operation more difficult.

Our results corroborate the results of others showing that inguinal hernia repair without mesh fixation is a safe alternative. Ferzli et al[3] conducted a randomized, prospective study comparing endoscopic TEP inguinal hernia repair with or without fixation of mesh and found that no increased incidence of recurrence occurred and that elimination of mesh fixation resulted in a savings of $120 per operation. Khajanchee et al[4] conducted a retrospective review of 172 endoscopic inguinal hernia repairs of which 105 were performed with fixation of the mesh, and 67 were performed without mesh fixation and found no increased risk of recurrence in the group in which the mesh was not fixed and that fixing the mesh was associated with an increased risk of neuropathic complications. As TEP without fixation may not be appropriate in everyone, we support the recommendation of Lau and Patil[5] that mesh fixation should be used in patients with larger hernial defects.

Avoiding tacks when repairing small to medium indirect inguinal hernias and smaller direct defects seems logical. One of the most surprising results from our study was that elimination of mesh fixation significantly decreased the

incidence of postoperative urinary retention. We believe that at least 2 possible explanations explain this result. First, eliminating fixation of the mesh might lead to decreased postoperative pain. Lau and Patil[5] conducted a case-control study comparing endoscopic TEP inguinal hernia repair with and without mesh fixation and found that postoperative pain levels upon coughing were decreased in patients in whom the mesh was not fixed ($P<0.05$). Postoperative pain levels in our study were also decreased in patients who did not receive mesh fixation compared with patients in whom the mesh was fixed; however, the differences were not statistically significant, which was likely due to the study being under powered. Mulroy[6] hypothesized that increased postoperative pain might lead to an increased incidence of urinary retention by increasing sympathetic tone impeding urination.

A second explanation for decreased urinary retention in patients that did not receive mesh fixation is that decreased pain leads to decreased use of postoperative narcotic analgesia. We observed that patients who underwent endoscopic TEP inguinal hernia repair without fixation of the mesh used significantly less narcotic analgesia in the immediate postoperative period. We, among others, have identified the use of high levels of postoperative narcotic analgesia as a risk factor for the development of postoperative urinary retention.[7] Thus, decreased pain might indirectly lead to decreased postoperative urinary retention by decreasing the amount of narcotic analgesia used by patients.

CONCLUSION

We recommend a tackless endoscopic TEP inguinal hernia repair as an alternative to endoscopic TEP inguinal hernia repair with mesh fixation in select patients. We do not believe that eliminating the fixation of the mesh in patients with smaller defects (<3 cm) will lead to an increased incidence of hernia recurrence; however, additional studies with larger numbers of patients and longer follow-up will be required to answer the question unequivocally.

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